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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/588,924	06/06/2000	Roger P. Jackson	00,063	9408

7590

08/21/2003

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EXAMINER

DAVIS, DANIEL J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/588,924

Applicant(s)

JACKSON, ROGER P.

Examiner

D Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

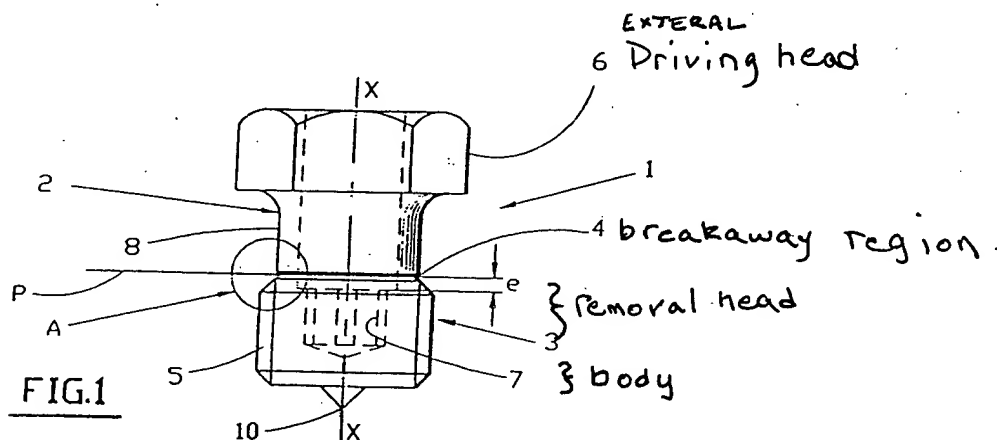
Claim Rejections - 35 USC § 102

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 9-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Gournay et al. (US 6,193,719 B1), or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Gournay when considering all embodiments and the teachings from the specification.

Regarding claims 1 and 9, Gournay discloses a "closure for use in conjunction with a medical implant having an inward threaded surface" (Fig. 1). See drawing below for an explanation of corresponding parts.



In this embodiment, Gournay does not illustrate an exterior/outwardly facing removal head. However, Gournay states, "In a general way, any type of print may be employed for the two component parts of the plug with, however, a preference for hexalobate prints. It is in this way possible to provide square, triangle, cruciform prints etc. for clamping and disassembly, *interior and exterior*, and any type of fracture initiating profile" (Col. 4, lines 46-51). Therefore, Gournay anticipates an exterior/outwardly facing removal head, even though the many possible combinations are not all illustrated in the drawings. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the removal head exterior/outwardly facing as a mere change in design in view of the aforesaid teaching. The driving head and the removal head may not receive and be manipulated by the same drive tool.

The head is designed to break off at a predetermined torque (Col. 1, lines 47-51).

Regarding the use of the implant to close a channel between two spaced arms, Figs. 12-13 illustrate a closure being used with an implant having arms.

Regarding claim 2, the driving head 6 is joined to the closure body by a breakaway region 4. The breakaway region 4 breaks away when a preselected force is applied to the driving head 6 (Col. 1, lines 47-51 and Col. 2, lines 34-35).

Regarding claim 4, the driving head and the removal head have different shapes, which prevent the installation tool from inadvertently gripping the removal head 6. Gournay teaches that the shape of either the driving head or the removal head may be of any shape (Col. 4, lines 46-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotrel (US 5,154,719) in view of Gournay.

Regarding claim 5, Cotrel discloses a system comprising an open headed implant having interiorly threaded 9 arms 6 in conjunction with a closure 10. The closure 10 has a cylindrical shaped body (Fig. 1) with a driving head 8 and a removal head 8 (the heads are one in the same). Cotrel fails to disclose that the driving head 8 has a different cross section from the removal head 8. Cotrel also fails to disclose a driving head that breaks away at a predetermined torque.

Gournay teaches a closure (Fig. 1) having a driving head 6 with a cross section different from that of the removal head. The driving head breaks away at a predetermined torque, (Col. 1, lines 46-51) which improves clamping torque precision (Col. 1, lines 52-60).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the closure 10 (Fig. 1) disclosed by Cotrel by adding the breakaway driving head 6 as taught by Gournay to improve clamping torque precision.

Regarding claim 6, the driving head taught by Gournay has a driving head 6 that is connected to the closure body (Fig. 1) by a breakaway region 4. The driving head 6 breaks away at a predetermined torque (Col. 1, lines 46-51).

Regarding claim 7, Gournay's removal head is centered between the closure body and driving head 6.

Regarding claim 8, Gournay teaches a driving head 6 having a cross section having a different polyhedral shape from that of the removal head. Cotrel discloses a hexagonal cross section. Gournay teaches that the shape of either the driving head or the removal head may be of any shape (Col. 4, lines 46-51).

Response to Arguments

Applicant's arguments have been carefully considered but are not persuasive. Although Gournay does not explicitly teach that the heads are different sizes "in order to avoid inadvertent driving of the removal head by the tool installing torturing head," as stated by Applicant, he does, nonetheless, teach that an external driving head and an external removal head have different sizes as illustrated in Figs. 12 and 13. Although the purpose for having the various sizes is irrelevant, the two sizes are necessary for the heads to separate when torqued.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel J Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
August 19, 2003



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700